

115TH CONGRESS
1ST SESSION

H. R. 2026

To improve patient access to emerging medication therapies by clarifying the scope of permitted health care economic and scientific information communications between biopharmaceutical manufacturers and population health decision makers.

IN THE HOUSE OF REPRESENTATIVES

APRIL 6, 2017

Mr. GUTHRIE introduced the following bill; which was referred to the
Committee on Energy and Commerce

A BILL

To improve patient access to emerging medication therapies by clarifying the scope of permitted health care economic and scientific information communications between biopharmaceutical manufacturers and population health decision makers.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Pharmaceutical Infor-
5 mation Exchange Act”.

1 **SEC. 2. FACILITATING EXCHANGE OF INFORMATION PRIOR**
2 **TO APPROVAL.**

3 Section 502(a) of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 352(a)) is amended—

5 (1) by redesignating subparagraph (2) as sub-
6 paragraph (3);

7 (2) by inserting after subparagraph (1) the fol-
8 lowing:

9 “(2) Health care economic information or scientific
10 information provided to a payor, formulary committee, or
11 other similar entity with knowledge and expertise in the
12 area of health care economic analysis carrying out its re-
13 sponsibilities for the selection of drugs for coverage, reim-
14 bursement, or other population-based health care manage-
15 ment, shall not be considered false or misleading or any
16 other form of misbranding under this paragraph, or a vio-
17 lation of section 505 of this Act or section 351 of the Pub-
18 lic Health Service Act, or otherwise prohibited pre-ap-
19 proval promotion of a drug, if it is based on competent
20 and reliable scientific evidence and relates to an investiga-
21 tional new drug or an investigational use of an approved
22 drug. In order for information relating to an investiga-
23 tional use of an approved drug to be provided pursuant
24 to this subparagraph, there must have been submitted to
25 the Secretary a supplemental application for approval of
26 such use, or the study or studies needed to support the

1 submission of a supplemental application for such use
2 must have been completed with the intention that a sup-
3 plemental application will be submitted to the Secretary
4 for approval of the use. For purposes of this subpara-
5 graph, scientific information includes clinical and pre-clin-
6 ical data and results relating to an unapproved drug ther-
7 apy, or drug indication, or other condition of use being
8 investigated or developed.”; and

9 (3) in subparagraph (3), as redesignated—

10 (A) by striking “(A)”; and

11 (B) by striking clause (B).

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